IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENXBIO INC. and THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, Plaintiffs, v. SAREPTA THERAPEUTICS, INC. and SAREPTA THERAPEUTICS THREE, LLC, Defendants.	Civil Action No. 20-1226-RGA

MEMORANDUM OPINION

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ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me are Defendants' motion for summary judgment and to exclude opinions (D.I. 190), Plaintiffs' motion for summary judgment of no invalidity under 35 U.S.C. § 101 (D.I. 193), Plaintiffs' motion for summary judgment that Defendants' infringing activities are not protected by the safe harbor of 35 U.S.C. § 271(e)(1) (D.I. 194), Plaintiffs' *Daubert* motion to preclude the testimony of Dr. Mark Kay on invalidity under 35 U.S.C. § 112 (D.I. 195), and Plaintiffs' *Daubert* motion to preclude the testimony of Carla Mulhern on hold-up (D.I. 196). I have considered the parties' briefing. (D.I. 191, 197, 207, 209, 217, 219). I heard oral argument on December 6, 2023.[1]

For the reasons set forth below, Defendants' motion for summary judgment is GRANTED IN PART, DENIED IN PART, and DISMISSED IN PART as moot. Plaintiffs' motion for summary judgment of no invalidity under 35 U.S.C. § 101 is DENIED. Plaintiffs' remaining motions are DISMISSED as moot.

I. BACKGROUND

U.S. Patent No. 10,526,617 ("the '617 patent") issued in January 2020. It expired in November 2022. (D.I. 191 at 4). The patent discloses "[a]deno-associated virus rh.10 sequences, vectors containing same, and methods of use." ('617 patent, Abstract).

Defendants use the AAV variant rh.74 in cultured host cells (D.I. 191 at 5) to make a gene therapy product referred to as SRP-9001 (D.I. 1 ¶ 1). The product is used to treat Duchenne muscular dystrophy. (D.I. 1 ¶ 1). Plaintiffs asserted the '617 patent against Defendants in

[1] Citations to the transcript of the argument, which is not yet docketed, are in the format "Hearing Tr. at ___."

September 2020, accusing Defendants of infringing claims 1–9, 12, 15, and 18–25. (D.I. 191 at 2; D.I. 197 at 2).

II. LEGAL STANDARD

A. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011). "[A] dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the non-moving party." *Id.* The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." Fed. R. Civ. P. 56(c)(1). The non-moving party's

evidence "must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance." *Williams*, 891 F.2d at 460–61.

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Patent-Eligible Subject Matter

Patentability under 35 U.S.C. § 101 is a threshold legal issue. *Bilski v. Kappos*, 561 U.S. 593, 602 (2010). Section 101 defines patent-eligible subject matter. It provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The Supreme Court recognizes three categories of subject matter that are not eligible for patents—laws of nature, natural phenomena, and abstract ideas. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). The purpose of these exceptions is to protect "the basic tools of scientific and technological work." *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*, 566 U.S. 66, 71 (2012) (citation omitted).

"A claim to otherwise statutory subject matter does not become ineligible simply because it recites a natural law," *Cleveland Clinic Foundation v. True Health Diagnostics LLC*, 760 F. App'x 1013, 1017 (Fed. Cir. 2019), as "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," *Mayo*, 566 U.S. at 71. In order "to transform an unpatentable law of nature [or natural phenomenon] into a patent-eligible

application of such a law [or natural phenomenon]," however, an inventor "must do more than simply state the law of nature [or natural phenomenon] while adding the words 'apply it.'" *Mayo*, 566 U.S. at 72 (emphasis omitted).

In *Alice*, the Supreme Court reaffirmed the framework laid out in *Mayo* "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." 573 U.S. at 217. The court must first determine whether the claims are directed to a patent-ineligible concept. *Id.* If the claims are so directed, then the court must look to "the elements of each claim both individually and as an ordered combination" to see if there is an "inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself." *Id.* at 217–18 (cleaned up). "To save a patent at step two, an inventive concept must be evident in the claims." *RecogniCorp, LLC v. Nintendo Co.*, 855 F.3d 1322, 1327 (Fed. Cir. 2017).

III. DISCUSSION

Claim 1 of the '617 patent is representative for the purpose of this opinion. It states:

> 1. A cultured host cell containing a recombinant nucleic acid molecule encoding an AAV vp1 capsid protein having a sequence comprising amino acids 1 to 738 of SEQ ID NO: 81 (AAVrh.10) or a sequence at least 95% identical to the full length of amino acids 1 to 738 of SEQ ID NO: 81, wherein the recombinant nucleic acid molecule further comprises a heterologous non-AAV sequence.

('617 patent at 437:55–63).

A. Defendants' Motions

1. Section 101

The parties dispute whether the asserted claims of the '617 patent are patentable under 35 U.S.C. § 101. At oral argument, the parties agreed that this is a question of law. (Hearing Tr. at 3:17–4:3). Plaintiff noted there are no disputes of fact between the parties. (*Id.* at 3:25–4:3). The § 101 issue is thus ripe for review.

Defendants argue that the '617 patent's asserted claims are not patent-eligible subject matter. (D.I. 191 at 11). Under step one of the *Alice* and *Mayo* framework, Defendants contend that the claims are directed to naturally occurring rh.10 sequences, which are not patentable. (*Id.* at 13). Defendants argue that the language of the '617 patent, the testimony of the patent's inventors, and the testimony of Plaintiffs' own expert support Defendants' position. (*Id.*). Defendants also argue that the specification describes the identification of the naturally occurring sequences as the inventors' only contribution over the prior art. (*Id.* at 16–17; *see also* D.I. 207 at 3–4; Hearing Tr. at 13:9–11 ("[C]ourts have talked about the directed to analysis as requiring an examination of the focus of the claimed advance over the [prior] art.")). Defendants contend that the patent claims monopolize use of the rh.10 sequences in a cultured host cell "for any research or commercial application." (D.I. 191 at 18).

Under step two, Defendants contend, "A person of ordinary skill in the art would have had all the tools needed to make and use cultured host cells containing nucleic acids encoding the full scope of the claimed capsid proteins." (*Id.* at 20 (quoting D.I. 192-1 at 485 of 806)). Defendants argue the additional claim elements "do not transform the naturally occurring rh.10 sequences into patent-eligible subject matter." (*Id.*). Defendants also contend that cultured host cells, recombinant nucleic acid molecules, heterologous non-AAV sequences, functional rep

genes, and plasmids were all well-known, routine, and conventional at the time of the invention. (*Id.* at 20–24). Defendants contend that the limitation "at least 95% identical" does not add anything inventive either. (*Id.* at 22). Defendants further argue that "the combination of [these] elements does not add an 'inventive concept' that amounts to 'significantly more' than the naturally occurring rh.10 sequences themselves." (*Id.* at 24).

Plaintiffs argue that Defendants did not apply the proper test to analyze whether the '617 patent's claims are patentable. (D.I. 209 at 8–10). Plaintiffs contend that step one of the § 101 inquiry must apply the "markedly different" test. (*Id.* at 4–7). The Federal Circuit has held, "A claim to a manufacture or composition of matter made from a natural product is not directed to the natural product where it has different characteristics and 'the potential for significant utility.'" *Nat. Alt. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1348 (Fed. Cir. 2019) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)). Applying the "markedly different" test, Plaintiffs argue that the claims' subject matter—"cultured host cells which must contain a recombinant nucleic acid molecule that encodes the sequence of AAVrh.10 (or a sequence at least 95% identical) and a heterologous, non-AAV sequence"—is not found in nature. (D.I. 209 at 7; *see also* Hearing Tr. at 7:2–22). Plaintiffs argue that the claimed cells are structurally and functionally different from naturally occurring sequences. Whereas naturally occurring rh.10 sequences are "inert," Plaintiffs contend the claimed cells have "significant functions," including "use in the triple transfection process that is critical to producing rAAV vectors for gene therapy." (D.I. 209 at 7; *see also* D.I. 197 at 10). Plaintiffs thus argue that the claimed cells are markedly different from the naturally occurring sequences. (D.I. 209 at 8).

Plaintiffs argue that Defendants improperly focused on only the rh.10 sequences. (*Id.* at 11–13). The § 101 inquiry, Plaintiffs contend, requires looking at claims in their entirety. (*Id.* at

11; *see also* D.I. 197 at 12–13). Plaintiffs argue that the '617 patent's specification indicates that the invention has utility in gene therapy; however, "It is only when they are combined with other components that the AAV sequences can be used in that manner." (D.I. 209 at 12).

Plaintiffs do not address step two of the *Alice/Mayo* inquiry. They only argue that the claims of the '617 patent are not directed to a natural product under step one. (*Id.* at 13–14; Hearing Tr. at 9:6–14).

Defendants respond that the "markedly different" analysis is not a separate standard, as it "aims to answer essentially the same question as the *Alice/Mayo* two-part test." (D.I. 217 at 6–7; Hearing Tr. at 14:10–17). Defendants contend that the "markedly different" analysis leads to the same result as the step one inquiry, arguing that the rh.10 sequences are not markedly different from sequences found in nature. (D.I. 217 at 8–9; *see also* D.I. 207 at 11–13). Defendants also argue that the distinguishing characteristics Plaintiffs identify—such as utility in gene therapy—are not recited in the claims. (D.I. 217 at 9–10; *see also* Hearing Tr. at 17:19–25). The claimed cells, Defendants contend, "do not have to do anything—other than 'contain' the naturally occurring rh.10 sequences." (D.I. 217 at 11; *see also* D.I. 207 at 4–5).

At oral argument, both parties stated that *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), is the most analogous case supporting their position. (Hearing Tr. at 19:24–20:4; *id.* at 20:25–21:1). Plaintiffs also rely on *Chakrabarty*, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part and rev'd in part*, 569 U.S. 576 (2013), *Natural Alternatives*, and *Kaneka Corp. v. Designs for Health, Inc.*, 2023 U.S. Dist. LEXIS 131412 (D. Del. Mar. 3, 2023). (*See* D.I. 197 at 10–13; D.I. 209 at 7–11; Hearing Tr. at 4:4–25:25). Defendants contend these cases are

distinguishable and instead compare the claims of the '617 patent to *ChromaDex, Inc. v. Elysium Health, Inc.*, 59 F.4th 1280 (Fed. Cir. 2023). (*See* D.I. 207 at 11–13; D.I. 217 at 7–12).

I begin with the "markedly different" framework of *Chakrabarty* and consider the asserted claims in their entirety. The '617 patent's claims disclose natural products, including the rh.10 sequence and a heterologous non-AAV sequence.[2] Such combinations of patent-ineligible subject matter are not necessarily invalid. In *Natural Alternatives*, for instance, the product claims were not directed to patent-ineligible subject matter even though they contained a combination of beta-alanine and glycine, two natural products. 918 F.3d at 1349. Importantly, however, the invention was different from the natural products it contained. "[T]he natural products [were] isolated and then incorporated into a dosage form with particular characteristics" that naturally occurring beta-alanine did not have. *Id.* at 1348–49.

The Supreme Court's decisions in *Chakrabarty* and *Myriad* further highlight the importance of change. In *Chakrabarty*, the invention was patentable because the inventor genetically engineered bacteria to make the bacteria "capable of breaking down multiple components of crude oil." 447 U.S. at 305, 310. Naturally occurring bacteria did not have this characteristic. *Id.* at 305. The cDNA claims in *Myriad* were patentable for a similar reason: the inventor removed non-coding regions from naturally occurring DNA sequences to create something new. 569 U.S. at 594–95. In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, on the

[2] Plaintiffs concede that at least some non-AAV sequences occur in nature. (*See* Hearing Tr. at 6:4–7) ("The other sequence could include something else that occurs in nature. Yes, I suppose it could. But it could also include something that does not occur in nature."); *id.* at 7:1–5 ("[T]he second sequence has to be from something that is not adeno-associated virus. So even if that were also a natural sequence from somewhere else, you would have to take two sequences from two different organisms and put them together, and that combination is not found in nature.")).

other hand, the inventor "did not alter the bacteria in any way," merely obtaining patent claims for a combination of naturally occurring bacteria strains. 333 U.S. 127, 128–32 (1948), *quoted in Myriad*, 569 U.S. at 591. These claims were invalid. *Id.*

I think the claims at issue are similar to the ineligible claims in *Funk Brothers*. Taking "two sequences from two different organisms and put[ting] them together" (*see* Hearing Tr. at 7:2–5) is no different than taking two strains of bacteria and mixing them together. The inventors of the '617 patent—unlike *Natural Alternatives*, *Chakrabarty*, and the eligible claims in *Myriad*—have not changed any of the claimed invention's naturally occurring components.[3] Plaintiffs do not suggest that the isolated rh.10 sequences are any different from those found in nature,[4] and isolation on its own is insufficient to create patent-eligible subject matter. *See Myriad*, 569 U.S. at 596 ("We . . . hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material."). Plaintiffs also do not argue that the claimed invention's non-AAV sequence or any other elements have been altered from their naturally occurring counterparts. (*See generally* D.I. 197 at 9–14; D.I. 209 at 4–14; D.I. 219 at 2–8). Without some change, the mere fact that the '617 patent's inventors combined natural products and put them in a host cell does not make the invention patentable under § 101.

[3] The claims at issue also differ from claim 20 in *AMP*. Concluding that claim 20, a method claim, was patentable, the Federal Circuit found that the inventor had altered "a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility." 689 F.3d at 1335–37. The Supreme Court did not review this claim on appeal. *See Myriad*, 569 U.S. at 595 ("[T]here are no method claims before this Court.").

[4] *See, e.g.*, D.I. 209 at 10 (discussing "the claimed cultured host cells" and "the natural sequence they incorporate").

Plaintiffs' contention that the claims of the '617 patent have utility for gene therapy is unpersuasive as well. Whereas the claim in *Kaneka* recited a reduced coenzyme with high purity and the specification explained how that claim differed from a naturally occurring reduced coenzyme, 2023 U.S. Dist. LEXIS 131412, at *13–15, Plaintiffs do not point to anything in the claims or specification that requires utility for gene therapy. Plaintiffs instead argue that "there is nothing in the legal standard requiring the 'significant utility' be recited in the claims." (D.I. 219 at 4). The specification mentions gene therapy in some parts—for instance, it states, "rAAV vectors of the invention are particularly advantageous in rAAV readministration and repeat gene therapy." ('617 patent at 4:65–67). The claims, however, do not disclose recombinant AAV vectors or those vectors' use for a particular purpose. (*See, e.g.*, *id.* at 437:55–63). The specification merely indicates that the claimed sequences are "useful in production of rAAV" (*id.* at 4:55–57), and Plaintiffs' briefing indicates that the claimed cultured host cells "are an integral part of the process to produce rAAV vectors for gene therapy" (D.I. 197 at 10). Because "it is improper to read a limitation from the specification into the claims," *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904 (Fed. Cir. 2004), Plaintiffs' arguments regarding utility for gene therapy do not support patentability.

Plaintiffs' position is also undermined by their own expert, who opined that the claims are not limited to use for gene therapy. (D.I. 208-1 at 13 of 339 ("[T]he claims of the '617 patent may cover certain steps in manufacturing a gene therapy product, but the patent's claims are not limited to that use.")). The expert opined that some of the claimed embodiments cannot even be used for gene therapy. (*Id.* at 9 of 339 ("None of the claims of the '617 patent say they require a gene therapy product, and certain cultured host cells infringing the claims would be incapable of

creating a final gene therapy product.")). The asserted claims thus "simply do not reflect the distinctions [Plaintiffs] rely on." *ChromaDex*, 59 F.4th at 1285.

Even if some embodiments of the claimed invention have utility for gene therapy, that only means the claims cover both eligible and ineligible subject matter. Such claims are not patentable. *See id.*[5] Because the claims "do not necessarily possess markedly different characteristics" (*id.*) from naturally occurring rh.10 sequences, I find that the claims are invalid under § 101.

In *ChromaDex*, the Federal Circuit stated that the § 101 inquiry could end here, but the court went on to apply the *Alice/Mayo* framework. *See id.* at 1285–86. I will do the same.

For the same reasons that the claims are not "markedly different" from natural products, I find that the claims are directed to a natural product—the rh.10 sequences. I thus turn to step two of the *Alice/Mayo* inquiry.

I agree with Defendants that the claims lack an inventive concept that could transform the claimed invention into patent-eligible subject matter. The claims themselves do not include an inventive concept. *See RecogniCorp*, 855 F.3d at 1327 ("To save a patent at step two, an inventive concept must be evident in the claims."); *Alice*, 573 U.S. at 221 ("[W]e must examine the elements of the claim to determine whether it contains an 'inventive concept' . . . ."). I also do not think that the specification reveals an inventive concept in the claims. The specification, in relevant part, states:

> The invention further encompasses AAV serotypes generated using sequences of the novel AAV serotypes of the invention, which are generated using synthetic, recombinant or other techniques known to those of skill in the art.

[5] At oral argument, Plaintiff conceded that claims are ineligible if they cover both patent-eligible and patent-ineligible subject matter. (Hearing Tr. at 23:6–10).

('617 patent at 15:1–4).

> The sequences, proteins, and fragments of the invention may be produced by any suitable means, including recombinant production, chemical synthesis, or other synthetic means. Such production methods are within the knowledge of those of skill in the art and are not a limitation of the present invention.

(*Id.* at 17:4–9).

> The methods used to construct any embodiment of this invention are known to those with skill in nucleic acid manipulation and include genetic engineering, recombinant engineering, and synthetic techniques.

(*Id.* at 18:57–61).

> The preparation of a host cell according to this invention involves techniques such as assembly of selected DNA sequences. This assembly may be accomplished utilizing conventional techniques.

(*Id.* at 25:38–41).

> Introduction of the molecules (as plasmids or viruses) into the host cell may also be accomplished using techniques known to the skilled artisan and as discussed throughout the specification.

(*Id.* at 25:48–51). These portions of the specification indicate that the claimed invention is made using well-understood, routine, and conventional steps. *See Mayo*, 566 U.S. at 79. Plaintiffs have not advanced any arguments to the contrary. (*See* D.I. 209 at 13–14; Hearing Tr. at 9:5–14).

I conclude that the asserted claims of the '617 patent are invalid under § 101 for claiming patent-ineligible subject matter. I thus grant Defendants' motion for summary judgment on this issue.

2. Non-Infringement

Defendants argue Dr. Paola Leone, Plaintiffs' expert, opined that to fall within the scope of the claims, sequences "must . . . meet several additional criteria" in addition to being "at least 95% identical" to the rh.10 sequences. (D.I. 191 at 6). Defendants contend that Dr. Leone

applied these "additional criteria" to her validity analysis, but not to her infringement analysis. (*Id.*). Defendants therefore argue that Plaintiffs have failed to proffer sufficient evidence to meet their burden of proof on infringement, so summary judgment of non-infringement should be granted. (*Id.* at 10).

At oral argument, I stated that "inconsistency is not a basis for me to grant non-infringement." (Hearing Tr. at 56:24–25). I therefore denied Defendants' motion for summary judgment of non-infringement. (*Id.* at 57:14–18).

3. *Daubert*

In light of my decision on Defendants' § 101 summary judgment motion, I do not need to resolve Defendants' *Daubert* arguments related to Dr. Heeb and Dr. Leone. I thus dismiss these parts of Defendants' motion as moot.

B. Plaintiffs' Motions

In light of my decision on Defendants' § 101 summary judgment motion, I deny Plaintiffs' § 101 summary judgment motion. I do not need to resolve Plaintiffs' motion on safe harbor under § 271(e)(1) or Plaintiffs' *Daubert* motions related to Dr. Kay and Dr. Mulhern. I thus dismiss these motions as moot.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment is GRANTED IN PART, DENIED IN PART, and DISMISSED IN PART as moot. Claims 1–9, 12, 15, and 18–25 of the '617 patent are invalid under 35 U.S.C. § 101. Plaintiffs' motion for summary judgment of no invalidity under § 101 is thus DENIED. Plaintiffs' remaining motions are DISMISSED as moot.

An appropriate order will issue.